

**PENDING CLAIMS IN THE LONG WAP APPLICATION
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1. A transgenic non-human mammal containing a DNA sequence stably integrated in its genome, wherein said DNA sequence comprises the 5' 4.2 kb *Sau3A* - *Kpn1* promoter of the mouse whey acidic protein gene, operably linked to a DNA sequence encoding protein C and a signal peptide, wherein said whey acidic protein promoter is specifically active in mammary cells and said signal peptide is effective in directing the secretion of said protein C into the milk of said transgenic mammal, wherein the activated form of said secreted protein C has an enzymatic activity of at least 50% as plasma-derived protein C, and wherein said transgenic mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows.

2. The transgenic non-human mammal of claim 1, wherein said protein C is human protein C, and wherein said DNA sequence encoding protein C further comprises regulatory elements located in the non-coding regions of the human protein C gene, wherein said regulatory elements are the AUG start codon, donor and acceptor splice signals, the secretion peptide, translation termination signal, transcription termination signal, and polyadenylation signal.

3. The transgenic non-human mammal of claim 1, wherein said DNA sequence encoding human protein C comprises the human protein C gene from 21 basepairs upstream of the protein C start codon to the *NheI* site in the 3' end of the protein C gene.

4. The transgenic non-human mammal of claim 1, wherein said DNA sequence comprises a DNA sequence comprising the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter ligated directly or by a linker to a fragment of the human protein C gene beginning 21 basepairs upstream of the protein C start codon and ending at the *NheI* site in the 3' end of the protein C gene.

6. A process for the ~~heterologous~~ ^{heterologous} production of protein C, comprising the steps of:

(A) providing a non-human transgenic mammal whose genome comprises a stably integrated DNA sequence comprising the 5' 4.2 kb *Sau3A* - *Kpn1* promoter of the mouse whey acidic protein gene, operably linked to a DNA sequence encoding a heterologous protein C and a signal peptide, said promoter being specifically active in mammary cells and said signal peptide being effective in directing the secretion of said protein C into the milk of said transgenic mammal, and wherein said transgenic mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows;

(B) producing milk from said transgenic mammal, wherein said milk contains said protein C, and wherein the activated form of said protein C has an enzymatic activity of at least 50% as plasma-derived protein C;

(C) collecting said milk; and

(D) isolating said protein C from said milk.

7. The process of claim 6, wherein said protein C is human protein C, and wherein said DNA sequence encoding protein C further comprises regulatory elements located in the non-coding regions of the human protein C gene, wherein said regulatory elements are the AUG start codon, donor and acceptor splice signals, the secretion peptide, translation termination signal, transcription termination signal, and polyadenylation signal.

8. The process of claim 6, wherein said DNA sequence encoding human protein C comprises the human protein C gene from 21 basepairs upstream of the protein C start codon to the *NheI* site in the 3' end of the protein C gene.

9. The process of claim 6, wherein said DNA comprises a DNA sequence comprising the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter ligated directly or by a linker to a fragment of the human protein C gene beginning 21 basepairs upstream of the protein C start codon and ending at the *NheI* site in the 3' end of the protein C gene.

11. A process for producing non-human transgenic mammals, comprising the steps of (A) providing a mixture containing a double-stranded DNA; (B) subjecting said mixture to anion-exchange high performance liquid chromatography to obtain purified double-stranded DNA; and thereafter (C) microinjecting an aqueous buffer solution containing said purified double-stranded DNA into an animal embryo, wherein said double-stranded DNA is selected from the group consisting of a double-stranded DNA comprising the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter, a double-stranded DNA comprising a fragment of the human protein C gene beginning 21 basepairs upstream of the protein C start codon and ending at the *NheI* site in the 3' end of the protein C gene, and a double-stranded DNA comprising a DNA sequence comprising the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter ligated directly or by a linker to a fragment of the human protein C gene beginning 21 basepairs upstream of the protein C start codon and ending at the *NheI* site in the 3' end of the protein C gene, wherein the activated form of protein C encoded by said double-stranded DNA has an enzymatic activity of at least 50% as plasma-derived protein C, and wherein said transgenic mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows.

12. A process for the production of a heterologous polypeptide in the milk of a transgenic non-human mammal, comprising the steps of:

(A) providing a non-human transgenic mammal whose genome comprises a stably integrated DNA sequence comprising the 5' 4.2 kb *Sau3A* - *Kpn1* promoter of the mouse whey acidic protein gene, operably linked to a DNA sequence encoding a heterologous ~~protein C~~ ^{polypeptide} and a signal peptide, said promoter being specifically active in mammary cells and said signal peptide being effective in directing the secretion of said polypeptide into the milk of said transgenic mammal;

- (B) producing milk from said transgenic mammal, wherein said milk contains said polypeptide;
- (C) collecting said milk; and
- (D) isolating said polypeptide from said milk.

14. A transgenic non-human mammal containing a DNA sequence stably integrated in its genome, wherein said DNA sequence comprises the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter, operably linked to a DNA sequence encoding a heterologous polypeptide whereby said polypeptide is expressed specifically in mammary cells of said transgenic mammal and said polypeptide comprises a signal peptide, said signal peptide being effective in directing the secretion of said polypeptide into the milk of said mammal.

16. An isolated DNA molecule which regulates the expression of a heterologous gene, wherein said DNA molecule consists of the 5' 4.2 kb *Sau3A* - *Kpn1* promoter of the mouse whey acidic protein gene.

17. The process of claim 12, wherein said transgenic non-human mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows.

18. The process of claim 17, wherein said transgenic non-human mammal is ^asheep.

19. The process of claim 17, wherein said transgenic non-human mammal is a goat.

20. The process of claim 17, wherein said transgenic non-human mammal is a cow.

21. The transgenic non-human mammal of claim 14, wherein said transgenic non-human mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows.

22. The mammal of claim 21, wherein said transgenic non-human mammal is ^asheep.

23. The mammal of claim 21, wherein said transgenic non-human mammal is a goat.

24. The mammal of claim 21, wherein said transgenic non-human mammal is a cow.